IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

GENOMIND, INC., on its own and on behalf of United ERISA Insureds 1-878,

Plaintiff,

v.

UNITEDHEALTH GROUP INC., et al. ,

Defendant.

Civil Action No. 2:21-cv-00373-WB

(FILED PUBLICLY)

UNITEDHEALTHCARE INSURANCE COMPANY AND UNITED HEALTHCARE SERVICES, INC.

Counterclaim-Plaintiffs

v.

GENOMIND, INC.

Counterclaim-Defendants

UNITEDHEALTHCARE INSURANCE COMPANY AND
UNITED HEALTHCARE SERVICES, INC.'S FIRST AMENDED COUNTERCLAIM

UnitedHealthcare Insurance Company and United Healthcare Services, Inc. (collectively, "United") bring this First Amended Counterclaim against Genomind, Inc. ("Genomind"), and allege as follows:

INTRODUCTION

1. Genomind received more than $13 million in overpayments from United, and Genomind refuses to return the money. Genomind billed for certain laboratory tests that were not covered by the express terms of United's health benefit plans, Genomind knew that the tests were not covered, Genomind sought payment anyway, and now Genomind will not return the

overpayments. The only way that Genomind would have been entitled to payment for those claims was if the claims were for services covered under United's benefit plans. The services were not covered and, thus, Genomind was not entitled to payment. United, therefore, brings this Employee Retirement Income Security Act ("ERISA") action to recoup the overpayments made to Genomind.

PARTIES

2. Plaintiff UnitedHealthcare Insurance Company is a corporation organized under the laws of the State of Connecticut, with its principal place of business in the State of Connecticut. UnitedHealthcare Insurance Company fully-insures and administers health plans.

3. Plaintiff United Healthcare Services, Inc. is a corporation organized under the laws of the State of Minnesota, with its principal place of business in the State of Minnesota. United Healthcare Services, Inc. fully-insures and administers health plans.

4. Genomind is a laboratory incorporated in Delaware and based in King of Prussia, Pennsylvania.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this Counterclaim because it raises a federal question under 28 U.S.C. § 1331, and this Court has venue pursuant to 28 U.S.C. § 1391, including because the incorrect payments at issue were made to Genomind, within this District.

FACTUAL BACKGROUND

United Insures or Administers Health Plans for Employers

6. United provides health care insurance or claim administration services under a variety of health plans and policies. United both funds and administers their fully insured plans. They pay claims submitted to these plans out of their own assets.

7. United's self-funded plans, or Administrative Services Only ("ASO") plans, are funded by contributions from their respective sponsor employers and member employees. United provides claim administration services for such plans pursuant to Administrative Services Agreements ("ASAs"), which identify the rights and obligations of United and the plan sponsors.

8. The ASAs for the ASO plans at issue confer on United the fiduciary responsibility and discretion to administer claims under the plans. In performing their duties as claims administrator, United acts as ERISA fiduciaries for these plans as that term is defined in ERISA.

9. Among other things, the ASAs give United the exclusive discretion and authority to monitor and pursue overpayments of plans funds. The ASAs state that the customers delegate to United the authority to recover overpayments resulting from fraud, waste, or abuse through litigation on behalf of the ASO plans.

10. The United ASAs typically state as follows:

> "Customer delegates to United the discretion and authority to develop and use standards and procedures for any recovery opportunity, including but not limited to whether or not to seek recovery, what steps to take if United decides to seek recovery, whether to initiate litigation or arbitration, the scope of such litigation or arbitration, which legal theories to pursue in such litigation or arbitration, and all decisions relating to such litigation or arbitration, including but not limited to, whether to compromise or settle any litigation or arbitration, and the circumstances under which a claim may be compromised or settled for less than the full amount of the potential recovery. In all instances where United pursues recovery through litigation or arbitration, Customer, on behalf of itself and on behalf of its Plans, will be deemed to have granted United an assignment of all ownership, title, and legal rights and interests in and to any and all claims that are the subject matter of the litigation or arbitration."

11. The ERISA plans at issue in this litigation include this or substantially similar language. Beyond the authority entrusted to United under their ASAs with plan sponsors, United has a concrete business interest in paying only valid claims under the ASO plans they administer.

12. United processes (or "adjudicates") and pays approximately one million claims every day. Due to volume, it is impossible for United's employees to review each and every

claim received. Accordingly, by necessity, and as is common industry practice, the process by which United adjudicates claims is largely automated.

13. United relies on providers to supply honest and accurate information with insurance claims, and require providers to attest to the accuracy of the claims they submit.

14. Genomind knows that United and other insurers and claims administrators adjudicate most claims automatically, and rely on providers to submit accurate claims.

The Specific Plan Terms at Issue Only Permit Payment for Covered Services

15. United's health plans include covered benefits for "in-network" services. A healthcare provider is "in network" if it has a contract with United under which it agreed to provide covered services to United members, and United agreed to pay agreed-upon amounts for those services.

16. A health plan may also have out-of-network benefits to cover a portion of the costs associated with receiving treatment from a provider that does not have a contract with United. Whether a member's plan includes out-of-network benefits is determined by the member or her or his employer.

17. At all times relevant to this Counterclaim, Genomind has been out-of-network as it pertains to United. Because of this, whether United is obligated to pay Genomind, if at all, is contingent on whether the member's health plan includes out-of-network benefits for the services provided by Genomind. Here, the benefit plans at issue did not cover tests that Genomind performed. Genomind knew this, but submitted the claims anyway, and it refuses to return the money.

18. In its Amended Complaint, Genomind alleges that it is entitled to payments from United on the basis of assignments that it received from United beneficiaries. As an alleged

assignee of benefits, Genomind claims to have stepped into the shoes of the assignor and is deemed to have knowledge of the relevant plan terms.

19. Each of the relevant health plans state that United is not responsible for paying of the Genomind tests at issue until October 1, 2019. The following are representative examples of the plan language in United's summary plan descriptions of ERISA-governed health plan that contains limitations on coverage and provisions regarding overpayments, including the following:

a. "Eligible expenses are the amount the Claims Administrator determines the Plan will pay for benefits. [The plan] has delegated to the Claims Administrator the discretion and authority to decide if a treatment or supply is a covered health service and how the eligible expense will be determined and covered under the Plan.

b. "Covered Health Services, Covered Services, or Covered Charges" are:

Those health services, including services, supplies or pharmaceutical products, that the Claim Administrator determines to be:

- Provided for preventing, diagnosing or treating sickness, injury, mental illness, substance use disorders or their symptoms;
- Consistent with nationally recognized scientific evidence as available and prevailing medical standards and clinical guidelines (as described below);

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- Not identified as an exclusion.

The Claims Administrator maintains clinical protocols that describe the scientific evidence, prevailing medical standards and clinical guidelines supporting its determinations regarding specific services.

c. "Eligible Expenses" mean:

For covered health Services, incurred while the Plan is in effect, eligible expenses are determined by the Claims Administrator, as stated below.

Eligible expenses are determined solely according to the Claims Administrator's reimbursement policy guidelines. The Claims Administrator develops the reimbursement policy guidelines, in the Claims Administrator's discretion, following evaluation and validation of all provider billings in accordance with one or more of the following methodologies:

- As indicated in the most recent edition of the Current Procedural Terminology (CPT), a publication of
- the American Medical Association, and/or the Centers for Medicare and Medicaid Services (CMS);
- As reported by generally recognized professionals or publications;
- As used for Medicare; and
- As determined by medical staff and outside medical consultants pursuant to other appropriate
- source or determination that the Claims Administrator accepts.

d. "Medically necessary" is defined as "A service or supply that is appropriate and required to prevent, diagnose or treat a condition or clinical symptoms in accord with generally accepted professional standards of practice that are consistent with

a standard of care in the community. The determination is made by the Claims Administrator."

e. The Plans include explicitly excludes coverage for certain services stating: "The Plan does not pay benefits for the following services, treatments or supplies even if they are recommended or prescribed by a provider or are the only available treatment for your condition." Specific exclusions include:

- Experimental, investigational or unproven services (as defined by the Plan), unless the Plan has agreed to cover them;
- Services that do not meet the definition of a covered health service (as defined by the Plan);
- Non-Covered Services: When a service is not a covered service under the Plan, all services related to that non-covered service are excluded.

20. In addition, United's plans are explicit in terms of United's right to recover overpayments from any entity who obtained the payment—including third parties, like Genomind in this case. For example, United's plans state: "If [the plan] pays for benefits for expenses incurred on account of a covered person, that covered person or any other person or organization that was paid, must make a refund to [the plan] if all or some of the:

- [The plan's] obligation to pay benefits was contingent on the expenses incurred being legally owed and paid by the covered person, but all or some of the expenses were not paid by the covered person or did not legally have to be paid by the covered person.
- Expenses were not paid by the covered person or did not legally have to be paid by the covered person;

- All or some of the payment [the Plan] made exceeded the benefits under the Plan; or
- All or some of the payment was made in error.
- ***

21. The foregoing terms are representative of those found in the other health plans that United insures or administers.

22. Based on this plan language, whether and to what extent a Genomind test is a covered service is dictated by the terms of each United member's individual health plan and United's payment policies. These policies are fully incorporated by reference into each health plan that United insures or administers.

Genomind Billed for Tests that It Knew Were Not Covered by United's Health Plans

23. Between at least May 15, 2015 and October 1, 2019, Genomind submitted thousands of claims for payment for pharmacogenomic panel testing that it allegedly performed for patients with United health benefit plans. United issued payments of approximately $13.6 million in connection with the claims submitted by Genomind to ERISA-government plans that United insures and/or administers.

24. The alleged pharmacogenomic panel testing performed by Genomind during this time period was not covered by the health plans administered by United and/or was otherwise an overpayment based on the terms of the relevant health benefit plans and the out-of-network benefits offered under each plan.

25. Indeed, until October 1, 2019, United's health plans did not cover pharmacogenetic multigene testing panels, including Genomind's Genecept® Assay as they were considered "unproven and/or not medically necessary for evaluating drug-metabolizer status." In

short, none of Genomind's pharmacogenetic testing billed to United prior to October 1, 2019, was covered under *any* of the health plans that United administers or insures. Genomind knew this.

26. On August 1, 2019, United issued a benefit coverage policy that would cover certain pharmacogenetic tests effective as of October 1, 2019.[1] Under the October 1, 2019 policy, United would pay for pharmacogenetic tests only if:

a. The member had a diagnosis of major depressive disorder or anxiety;

b. The member has failed at least one prior medication to treat their condition; and

c. A multi-gene panel has no more than 15 relevant genes.

27. Genomind was fully aware that United did not cover any of the pharmacogenetic tests that Genomind billed to United before October 1, 2019, and that United considered such tests to lack established efficacy and not medically necessary.

28. Genomind has characterized the October 1, 2019, policy as a "change" in United's previously held position regarding pharmacogenomics testing coverage, confirming that Genomind knew all along that its tests were not covered benefits under the terms of United's health benefit plans until, in certain circumstances, October 1, 2019.

29. For example, on August 9, 2019, [redacted]

[1] The October 1, 2019, policy is attached as Exhibit 3 and is fully incorporated by reference.

30. Similarly, during an August 23, 2019 phone call with Genomind representatives, United confirmed that Genomind's Genecept Assay® test would be a covered service only *after* October 1, 2019, provided all the requirements of its newly announced policy were met.

31. The same day, Dr. Malin corresponded with Kathryn Stough, United's National Lab Program Manager, copying Genomind's Chief Medical Officer, Dr. David Krause. In the email, Dr. Malin stated: "This email is to introduce you [Stough] to Genomind who have a test that our PGx policy will now cover *as of 10/1*." (Emphasis added.)

32. Indeed, internal documents produced by Genomind in this litigation confirm that Genomind understood that United's ERISA plans did not cover multi-gene panel testing until October 1, 2019. For example, in an email chain dated August 1, 2019, [redacted]

33. Similarly, in an August 1, 2019 email [redacted]

34. Despite knowing that its tests were not covered or reimbursable under United's plans, Genomind submitted thousands of claims for reimbursement to United and received millions of dollars in reimbursements. Genomind has refused to return the payments despite knowing it is not entitled to any of the money under United's plans.

35. In addition to the lack of coverage under the relevant health plans, many of the tests that Genomind allegedly performed and billed to United before October 1, 2019, were improperly coded. Specifically, Genomind billed codes for single-gene tests when, in reality, it had performed multi-gene panels. On information and belief, Genomind did this to hide the fact that it was performing multi-gene panel testing from United in order to increase the likelihood that the claims would be inadvertently paid in an automated fashion by United in contravention of its clear policy to the contrary.

36. Multi-gene panels often introduce error and produce unreliable results. Because multi-gene panels require additional, follow-up validation testing, relevant United payment policies in effect before October 1, 2019, provided that multi-gene panels were not medically necessary, unproved, and not covered under the terms of any health plans that United insured or administered. Until that point, there was insufficient scientific evidence to establish the medical necessity of such tests.

37. All of the health plans that United insures or administers require members (or, in the case of valid assignments, assignees) to submit claims that are complete, accurate, and truthful.

38. Genomind's submission of claims for single-gene panels that actually corresponded to multi-gene panels rendered those payment claims improper and ineligible for payment.

39. Erroneous coding is an additional basis for United to seek return of the at-issue overpayments, in addition to their lack of eligibility for coverage prior to October 1, 2019.

40. Similarly, Genomind billed United using CPT codes for tests for which Genomind did not have appropriate CLIA certification. United performed an analysis of claims submitted

by Genomind versus the CLIA lab certification codes CMS certified for Genomind to perform. Through that analysis United determine that between May 5, 2015 and October 31, 2019, Genomind billed United for thousands of tests that it was not CLIA certified to perform and received over $5 million in reimbursements for those tests from United's ERISA plans.

41. Under United's ERISA plans, Genomind is not entitled to reimbursement for tests for which it did not have CLIA certification.

42. On January 31, 2020, United sent Genomind a letter outlining the overpayments that Genomind received for tests for which it did not have appropriate CLIA certification. Genomind has refused to return those payments.

43. United only recently discovered the overpayments that are the subject of this Counterclaim and has informed Genomind of its obligation to repay them promptly and completely.

44. Genomind has refused to repay any part of the subject overpayments.

45. The parties have agreed to, and the Court has entered, a protective order in this case that allows the parties to exchange claims information in a confidential matter.

46. United has provided Genomind with a list of claims for which it issued payments to Genomind that were not authorized under the relevant health benefit plans. United, and its self-funded plans, are entitled to recover these funds.

COUNT I
VIOLATION OF ERISA SECTION 502(A)(3)

47. United realleges all preceding paragraphs as if fully set forth herein.

48. United acts as a claims administrator for certain health benefit plans governed by ERISA, 29 U.S.C. § 1001, et seq.

49. United has been delegated by the plan administrator of each of the relevant ERISA governed health benefit plans at issue (the "ERISA Plans") the discretionary authority to review and decide on claims for benefits under the ERISA Plans.

50. ERISA Section 502(a)(3) permits fiduciaries to enjoin any acts or practices that violate any provisions of the ERISA Plans, and to obtain other appropriate relief to redress such violations or enforce provisions of the ERISA Plans.

51. United has also been authorized by the relevant plan sponsors and ERISA plans the authority to recover overpayments made to Genomind.

52. United has standing to sue under ERISA § 502(a)(3) to obtain appropriate equitable relief and to enforce the terms of the ERISA Plans.

53. Genomind received millions of dollars in reimbursements from United ERISA plans for services that it knew were not covered by those ERISA plans.

54. Genomind engaged in improper and/or incorrect billing, which caused United to pay amounts in excess of the amounts owed under the terms of the ERISA Plans, and for services that are not covered under the terms of the ERISA Plans.

55. Genomind also recived millions of dollars in reimbursements from United ERISA plans for tests for which Genomind did not have appropriate CLIA certifications.

56. The health benefit plans, by their terms, cover only medically necessary and covered services and require the return of overpayments and amounts that were erroneously paid.

57. This includes seeking payment for pharmacogenetic testing prior to October 1, 2019 which was not covered under the terms of the health benefit plans at issue.

58. In total, Genomind has received, and improperly refuses to return, more than $13 million.

59. United seeks equitable restitution to cover the assets that Genomind has unlawfully obtained because of the conduct described herein.

60. United seeks an Order imposing an equitable lien or constructive trust on the assets that Genomind received in the form of overpayments.

61. United also seeks an Order restoring—individually and on behalf of the ERISA plans—the sums held in constructive trust by Genomind.

PRAYER FOR RELIEF

WHEREFORE, United respectfully requests judgment in its favor granting the following relief: a) actual and consequential damages in an amount to be determined at trial, plus interest; b) an order obligating Defendants to disgorge the proceeds of the receipt of overpayments; c) equitable relief, as described herein; e) an award of the Plaintiffs' costs, including reasonable attorney's fees, in accordance with contractual provisions and ERISA § 502(g)(1); and g) any other relief deemed just, proper, and/or equitable.

Dated: March 2, 2022

By: */s/ Gregory S. Voshell*

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